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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,140	10/31/2005	Eva Kontsekova	SONN:065US	5448

32425 7590 08/17/2007  
FULBRIGHT & JAWORSKI L.L.P.  
600 CONGRESS AVE.  
SUITE 2400  
AUSTIN, TX 78701

EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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08/17/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/521,140	Applicant(s) KONTSEKOVA, EVA	
	Examiner Olga N. Chernyshev	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 24-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-28 and 31-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignment, 2 pages.</u>       |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group I in the reply filed on June 11, 2007 is acknowledged. The traversal is on the ground(s) that the restriction requirement fails to establish that the groups I and II do not relate to a single inventive concept. This is not found persuasive because the restriction requirement with respect to unity of invention and PCT Rule 13.1 was fully explained at pp. 2-3 of Paper mailed on April 11, 2007. Briefly, inventions of Groups I and II encompass different products (a protein and a transgenic animal), and as such they are not among the combination of categories, which support the unity of invention. Moreover, Applicant's own citation of prior art serves as a reference that the fragments of tau were known before the filing of the instant application, see IDS filed on October 31, 2005. Applicant is further advised that claim 33 is an improper dependent claim as it fails to limit the subject matter of the base claim 24, see 37 CFR 1.75(c), and the "Infringement Test" for dependent claims in MPEP § 608.01(n). Therefore, the fact the claim 33 recites the subject matter of claim 24 cannot serve as a basis for rejoining Groups I and II.

Applicant is further advised that truncated tau molecules of four different types have different structure, require separate sequence search and are not obvious over each other; therefore, the election of species for the purpose of examination is proper. Applicant is reminded that if the generic claim is found to be allowable, all species would be examined.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 26-28 and 31-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking

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claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 11, 2007.

3. Claims 24 and 29-30, in so far as they are drawn to a type IIA truncated tau molecule, are under examination in the instant office action.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 24 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ghetti et al., WO9962548, 1999.

Claims 24 and 29-30 encompass an isolated tau molecule comprising the amino acid sequence of SEQ ID NO: 15. Document of Ghetti et al. discloses a form of tau protein, which has an amino acid sequence 100% identical to the instant claimed peptide of SEQ ID NO: 15 (see copy of the sequence alignment attached to the instant office action), thus fully anticipating the instant invention.

***Conclusion***


6. No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Y. Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

August 14, 2007

&lt;!--StartFragment--&gt;RESULT 7

AAY15200

ID AAY15200 standard; protein; 351 AA.

XX

AC AAY15200;

XX

DT 28-FEB-2000 (first entry)

XX

DE Human Tau protein.

XX

KW Human Tau gene; neurofibrillary tangle formation; abnormal tau filament;

KW brain; mutation; phosphorylation; isoform ratio; diagnosis; tauopathy;

KW treatment; neurodegenerative disorder; Fronto-Temporal Dementia;

KW Familial Multiple System Tauopathy with presenile Dementia; MSTD;

KW Pick's Disease; Progressive Supranuclear Palsy; PSP; Alzheimer's Disease;

KW Corticobasal Degeneration; CD; Prion Protein Cerebral Amyloid Angiopathy;

KW cognitive disorder.

XX

OS Homo sapiens.

XX

FH Key Location/Qualifiers

FT Protein 1. .351

FT /label= Tau\_protein

FT /note= "Microtubule related protein"

XX

PN WO9962548-A1.

XX

PD 09-DEC-1999.

XX

PF 28-MAY-1999; 99WO-US012036.

XX

PR 01-JUN-1998; 98US-0087557P.

XX

PA (ADRE-) ADVANCED RES &amp; TECHNOLOGY INST.

XX

PI Ghetti B, Spillantini MG, Murrell JR, Goedert M, Farlow MR;

PI Klug A;

XX

DR WPI; 2000-086858/07.

DR N-PSDB; AAZ29262.

XX

PT Diagnosing a tauopathy, especially a Fronto-Temporal Dementia.

XX

PS Disclosure; Page 85; 90pp; English.

XX

CC The present amino acid sequence is a form of human Tau protein. There are  
 CC six tau isoforms, expressed in the normal adult brain with a slight  
 CC preponderance of those with 3 repeats over those with 4 repeats.

CC Mutations in the tau gene affects phosphorylation and leads to formation  
 CC of neurofibrillary tangles and alters the tau isoform ratio. The

CC increased ratio of 4:3 repeat and abnormal tau filaments is closely

CC related to neurodegenerative disorders. This sequence can be used for

CC diagnosis and treatment of tauopathies, like Fronto-Temporal Dementia,

CC Familial Multiple System Tauopathy with presenile Dementia (MSTD), Pick's

CC Disease, Progressive Supranuclear Palsy (PSP), Corticobasal Degeneration

CC (CD) or Alzheimer's Disease. A composition that decreases the ratio of

CC 4:3 repeat tau isomers, along with an agent for treatment of a cognitive

CC disorder, is useful for treating a tauopathy. It may also be useful in

CC diagnosis of Prion Protein Cerebral Amyloid Angiopathy and other prion

CC protein associated disease characterized by abnormal tau filament

CC formation

XX

SQ Sequence 351 AA;

Query Match 100.0%; Score 1108; DB 3; Length 351;

Best Local Similarity 100.0%; Pred. No: 3.8e-76;

Matches 210; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

QY 1 IATPRGAAPPQGKQANATRIPAKTPPAPKTPSSGEPKSGDRSGYSSPGSPGTPGSR 60

|||||

Db 93 IATPRGAAPPQGKQANATRIPAKTPPAPKTPSSGEPKSGDRSGYSSPGSPGTPGSR 152

QY 61 RTPSLPTPTREP KKVAVVRTPPKSPSSAKSRLQTAPVMPDLKNVSKIGSTENLKHQP 120

|||||

Db 153 RTPSLPTPTREP KKVAVVRTPPKSPSSAKSRLQTAPVMPDLKNVSKIGSTENLKHQP 212

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Qy      121 GGGKVQIVYKPVDSLKVTSKCGSLGNIHHKPGGGQVEVKSEKLDKDRVQSKIGSLDNIT 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      213 GGGKVQIVYKPVDSLKVTSKCGSLGNIHHKPGGGQVEVKSEKLDKDRVQSKIGSLDNIT 272
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||

Qy      181 HVPGGGNKKIETHKLTFRENAKAKTDHGAE 210
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      273 HVPGGGNKKIETHKLTFRENAKAKTDHGAE 302
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
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